REMARKS

Claims 1-29 are pending in this application. The Examiner has withdrawn claims 8-13 and 23-29 from consideration. Claims 1, 13 and 20 have been amended to clarify claim language by explaining in more detail the steps of the claimed methods, which were in implicit from the specification. Therefore, the scope of claims 1, 13 and 20 have not been narrowed by these amendments.

Objections

The disclosure was objected to because page 14 contained two hyperlinks.

Applicants have amended the specification to correct these informalities. No new matter was introduced. Applicants respectfully request that these objections be withdrawn.

Rejection under § 112, second paragraph

Claims 1-7, 13-19, 20, 21, and 22 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

Claims 1-7 and 13-19 were rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The Examiner argued that the omitted steps were: the actual steps required to predict resistance that must be

performed by the trained neural net. Applicants respectfully traverse. However, in an effort to expedite prosecution, Applicants have amended claims 1 and 13 to make explicit what was previously implicit from the specification about how the step of predicting is performed without narrowing the relevant claim element. Applicants therefore respectfully request that these rejections be withdrawn.

The Examiner also argued that the method is lacking steps wherein a sample is obtained, and the genetic information of the pathogen is obtained from the sample. However, the primary purpose of the requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. M.P.E.P. § 2173. The claims recite "providing a determined genetic sequence from the pathogen," and the specification defines a pathogen on page 7 as a causing a pathological condition in an organism, thus it is clear to the public that the genetic information of the pathogen is obtained from a sample that contains the pathogen. Applicants therefore respectfully request that these rejections be withdrawn.

Claims 1, 13 and 20 were rejected as being unclear as to what exactly constitutes a trained neural network. Applicants respectfully traverse. However, in an effort to expedite prosecution, Applicants have amended claims 1, 13, and 20 to make explicit what was previously implicit from the specification about how the neural network is trained without narrowing the relevant claim element. Furthermore, in order to meet the requirements of 35 U.S.C. § 112, second paragraph, the claims must define the patentable subject matter with a reasonable degree of particularity and precision. M.P.E.P. § 2173.02. If the scope of the invention sought to be patented can be

determined from the language of the claims with a reasonable degree of certainty, then a rejection under 35 U.S.C. § 112, second paragraph, is not appropriate. See In re Wiggins, 488 F.2d 538, 179 U.S.P.Q. 421 (C.C.P.A. 1973). Claims 1, 13, and 20 as amended, describe broad methods that include a trained neural network that is not limited to a particular amount of data, a particular amount of training, or a particular method of training. The skilled artisan, using the teachings of the prior art, will easily recognize that numerous ways of training may be used in the methods of the invention with the specification providing examples of many of these methods and thus determine the scope of the claims with a reasonable degree of precision. Thus, Applicants respectfully request that these rejections be withdrawn.

Claims 1, 13 and 20 were rejected because the metes and bounds of the phrase "a determined genetic sequence" are unclear. Applicants respectfully traverse. The Federal Circuit has decided that the definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, e.g., In re Marosi, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983). Claims 1, 13, and 20, as amended, describe broad methods that include providing a determined genetic sequences. The type of genetic sequence data required, for example, may depend on the pathogen and the therapeutic agent. One of skill in the art, in light of the instant disclosure and the prior art would be able to decide

the scope of the phase "determined genetic sequence" based on the pathogen or disease of interest and the therapeutic agent of interest. Thus, the metes and bounds of this phrase are clear when it is analyzed as required by the Federal Circuit and Applicants respectfully request that these rejections be withdrawn.

Claims 21 and 22 were rejected because the claims recite that the "disease is a pathogen" which is not strictly accurate. Applicants respectfully traverse. Applicants respectfully direct the Examiner to page 7, line 18-20, wherein the term disease is defined as a pathogen or malignant cell. Thus, Applicants respectfully request that these rejections be withdrawn.

Rejections under § 102

Claims 1-5 and 13-18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Comanor et al for the reasons described on page 4 of the Office Action. Applicants respectfully traverse these rejections.

A rejection under § 102 is only proper when the claimed subject matter is identically described or disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *see also* M.P.E.P. § 706.02(a) ("For anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly."). Importantly, each and every element of a claim must be set forth in the prior art reference for there to be anticipation. *See* M.P.E.P. § 2131.

Comaner et al does not teach a neural network that is trained using a training data set comprising members that correspond to at least one genetic mutation that correlates to a phenotypic change that causes a change in resistance of the pathogen

to th therapeutic agent. The Examiner argues that Comaner describes a set of data that can be used which includes a genetic sequence as one of many types of data and knowledge of sensitivity or resistance to a particular treatment as another type of data. This is not the same thing, however, as data that correlates at least one genetic mutation to a phenotypic change. Furthermore, Comaner does not teach the use of this direct correlation.

The Examiner also argues that Comaner teaches that genetic sequence data is used to train and develop a statistical model. At best, however, Comaner generically lists genetic mutations as one of many types of patient data that may be used in the method of Comaner. Comaner does not specifically teach how to use a genetic mutation and additionally has not enabled or even described a method of using a genetic mutation in neural network, as assumed by the Examiner. To constitute an anticipatory reference, the prior art must contain an enabling disclosure. *Chester v. Miller*, 906 F.2d at 1546 n.2, 15 U.S.P.Q.2d at 1336 n.2 (Fed. Cir. 1990); *see also Titanium Metals Corp. of America v. Banner*, 778 F.2d at 781, 227 U.S.P.Q. at 778 (Fed. Cir. 1985).

Finally, Comaner does not teach a method of predicting resistance of the **pathogen** to the therapeutic agent using the determined genetic sequence and the trained neural network to identify at least one mutation of the determined genetic sequence that confers resistance to the therapeutic agent. Comaner only teaches resistance of a **patient** based on various types of patient data. Thus, Applicants respectfully request that these rejections be withdrawn.

Claims 1-7 and 13-22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Draghici et al for the reasons described on pages 4-5 of the Office Action. Applicants respectfully traverse these rejections.

As described above, a rejection under ' 102 is only proper when the claimed subject matter is identically described or disclosed in the prior art. Draghici does not teach a neural network that is trained using a training data set comprising members that correspond to at least one genetic mutation that correlates to a phenotypic change that causes a change in resistance of the pathogen to the therapeutic agent and using this trained neural network to identify at least one mutation of the determined genetic sequence that confers resistance to the therapeutic agent. As described by the Examiner, Draghici uses the genetic sequence to model the protein structure and not to correlate the mutations of the genetic sequence to a phenotypic change. Thus, Draghici does not identically describe the present invention and Applicants respectfully request that this rejection be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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